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Example 1

One gram of 1-[2,3-dihydro-1-(O-methylphenacyl)-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl]-3-(m-tolyl)urea (hereinafter referred to as YM022), 3.5 g of hydroxypropyl methylcellulose (HPMC2910: made by Shin-Etsu Chemical Co., Ltd., trade name: TC-5E) which acts as a polymer base, and 0.5 g of a polyoxyethylene hydrogenated castor oil (made by Nikko Chemicals Co., Ltd., trade name: HCO-60) which acts as a nonionic surfactant were dissolved in a mixed solution of dichloromethane/methanol (8:2), and the resultant solution was subjected to spray drying to obtain the powder of a solid composition.

As a result of determination by the powder X-ray diffraction method, the YM022 in the powder was found not to be crystalline but to be amorphous. The obtained powder was further dispersed in purified water to obtain fine particles with a particle size of 0.1 to 1 μm. The particle size distribution is shown in Figure 2.

In Figure 2, the relative distribution of a volume-average diameter of the particles with specific particle sizes is shown as a bar graph, and the cumulative distribution is shown as a curve. The relative distribution of a volume-average diameter of the particles is shown on the left ordinate axis, and the cumulative distribution of a volume-average diameter of the particles is shown on the

right ordinate axis. Note that the notation system for the cumulative distribution in Figures 3, 4, 7 and 8 is the same as in Figure 2.

Comparative Example 1

The solid composition in Comparative Example 1 is different from that in Example 1 in that it does not contain a nonionic surfactant.

One gram of YM022 and 3.5 g of hydroxypropyl methylcellulose were dissolved in a mixed solution of dichloromethane/methanol (8:2), and the resultant solution was subjected to spray drying to obtain the powder of a solid composition. As a result of determination by the powder X-ray diffraction method, the YM022 in the powder was found to be amorphous. The obtained powder was dispersed in purified water to determine the particle size. The particle size distribution is shown in Figure 3. The particle size was distributed from 2 to 100 μm, and fine particles with a particle size of 1 μm or less were not produced.

CLAIMS

1. A solid composition with improved solubility and absorbability comprising an extremely hardly water-soluble drug with a solubility of less than 10 μg/ml in an amorphous state, a polymer base and a nonionic surfactant.

2. The solid composition according to claim 1, characterized in that fine particles with a particle size of 1 μm or less comprising said extremely hardly water-soluble drug that maintains the amorphous state are formed when said solid composition is dispersed in a liquid.

3. The solid composition according to claim 1, wherein said solubility is the solubility in water, a first liquid or a second liquid, with a temperature of 37°C.

4. The solid composition according to claim 1, wherein said solid composition comprises 1 part by weight of said extremely hardly water-soluble drug, 0.5 to 20 parts by weight of said polymer base and 0.1 to 3 parts by weight of said nonionic surfactant.

5. The solid composition according to claim 4, wherein the weight ratio of said polymer base to said extremely hardly water-soluble drug is from 1 to 10.

6. The solid composition according to claim 4, wherein the weight ratio of said nonionic surfactant to said extremely hardly water-soluble drug is from 0.25 to 1.5.

7. The solid composition according to claim 2, wherein said fine particles comprise 1 part by weight of said extremely hardly water-soluble drug, 0.01 to 1 part by weight of said

polymer base and 0.1 to 0.5 part by weight of said nonionic surfactant.

8. The solid composition according to claim 7, wherein the weight ratio of said polymer base to said extremely hardly water-soluble drug is from 0.1 to 0.6.

9. The solid composition according to claim 7, wherein the weight ratio of said nonionic surfactant to said extremely hardly water-soluble drug is from 0.1 to 0.4.

10. The solid composition according to claim 1 or 7, wherein said polymer base comprises one or more selected from the group consisting of a water-soluble polymer and an enteric polymer.

11. The solid composition according to claim 10, wherein said water-soluble polymer comprises one or more selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose and hydroxyethyl cellulose.

12. The solid composition according to claim 1 or 7, wherein said nonionic surfactant comprises one or more selected from the group consisting of a polyoxyethylene hydrogenated castor oil, a polyoxyethylene sorbitan higher fatty acid ester and polyoxyethylene polyoxypropylene glycol.